IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA, *et al.*, *ex rel.* STAN ELLIS	:	
v.	:	**CIVIL ACTION NO. 16-1582**
CVS HEALTH CORPORATION, *et al.*	:	

MCHUGH, J. **May 2, 2023**

MEMORANDUM

This *qui tam* action is brought by relator Stan Ellis on behalf of the United States of America and various states and municipalities against CVS Health Corporation ("CVS") and seven corporate subsidiaries.[1] Plaintiff-Relator brings claims under the federal False Claims Act ("FCA") and numerous state and municipal analogues, alleging that CVS knowingly sought reimbursement from federal, state, and municipal payors for pharmaceuticals that had lost their efficacy as a result of flash freezing during the shipping process.[2] The Defendants move to dismiss the case in its entirety. The motion will be granted in part. Claims against the corporate subsidiaries will be dismissed because Plaintiff has failed to specify what role they played. As to CVS itself, several state and municipal claims must be dismissed. Plaintiff's "legal falsity" claims must also be dismissed, because the regulations on which Plaintiff relies do not support the conclusions he advances. But as to the three specific drugs for which the manufacturers warned

[1] The United States and participating states did not decline intervention until August 2022. ECF 20. Thereafter, the parties stipulated to various extensions, and the pending motion first became ripe on February 20, 2023. ECF 43.

[2] Plaintiff also brings a claim for False Claims Act conspiracy (Count Three). Both sides agree that this claim should be dismissed with prejudice, so I will not address it further in this memorandum.

against freezing the medications, Plaintiff has plausibly alleged a "worthless services" theory of liability. Those claims may proceed, and Plaintiff will be given an opportunity to amend the other federal FCA claims. In all other respects, the motion is denied.

I. Factual Allegations

Among other lines of business, Defendant CVS ships pharmaceuticals to patients, doctors, and medical clinics. Compl. at ¶¶ 28, 31, ECF 1. Plaintiff alleges that CVS agreed to and was required to ship temperature-sensitive pharmaceuticals using "cold chain" methods and protocols to ensure that the integrity of those products remained stable throughout the shipping process. *Id.* at ¶ 2.[3] But according to Plaintiff, CVS has used, and continues to use, an EPS Styrofoam packing system to ship temperature-sensitive pharmaceuticals that allows those products to flash freeze, resulting in the partial or total loss of their efficacy. *Id.* at ¶¶ 28, 35. While the Complaint implies that this issue was widespread among CVS-shipped pharmaceuticals, the Complaint identifies only three specific pharmaceuticals by name: Humira, Enbrel, and Copaxone. *Id.* at ¶¶ 36-42, 82-87. The medication guides for these three pharmaceuticals all advise that they should not be frozen. *Id.* at ¶¶ 83-86.

Relator Stan Ellis was the Vice-President of Sales of Coldkeepers, LLC from 2008 to 2015. *Id.* at ¶ 29. Coldkeepers manufactures and sells insulated thermal packages for the transport and shipping of temperature-sensitive items, including pharmaceuticals. *Id.* In 2010, Ellis began contacting CVS to market a patented urethane foam flexible cooler for shipping temperature-sensitive drugs. *Id.* at ¶ 31. Ellis learned that CVS was using an EPS Styrofoam packing system, which he knew caused the flash freezing of certain pharmaceuticals, and he discussed this issue with CVS executives. *Id.* at ¶¶ 31-32. One executive, Brad Zimmerly—then the Director of

[3] Plaintiff defines an "unbroken cold chain" as "an uninterrupted series of storage and distribution activities which maintain a specified temperature range." *Id.*

Logistics—admitted that CVS had received customer complaints from patients who had received frozen medication and that CVS had trained its customer service representatives to advise patients to discard any medications that appeared to have been frozen and obtain replacements. *Id.* at ¶¶ 32-33.

In 2011, as part of the marketing discussions between Ellis and CVS, CVS conducted two rounds of independent testing of its shipping method for Humira, Enbrel, and Copaxone. *Id.* at ¶¶ 36-42. The tests showed that the EPS Styrofoam packing system would flash freeze pharmaceuticals in the first ninety minutes after they were packed, and that the pharmaceuticals would then thaw out over time. *Id.* at ¶¶ 39, 42. CVS contemplated doing further testing to determine if the flash-frozen medication had lost potency or efficacy, but chose not to do so, in part because of the cost of such testing. *Id.* at ¶ 43.

Plaintiff alleges that, by at least March 2012, several CVS executives were aware of the flash freezing problem with the EPS Styrofoam system, and the Vice-President of Strategic Procurement wrote in a March 2012 email to Ellis that CVS was not questioning the results of the 2011 tests. *Id.* at ¶ 44.

In October 2012, CVS began a Request for Proposal ("RFP") process for an alternative to the EPS Styrofoam packing system. *Id.* at ¶ 45. Coldkeepers submitted a proposal for CVS to implement Coldkeepers' urethane foam flexible cooler, and Coldkeepers won the CVS contract around March 2013. *Id.* at ¶¶ 46-47. CVS then began using Coldkeepers' product at some of its shipping facilities, but Plaintiff alleges that some CVS facilities continued to use the EPS Styrofoam packing system instead. *Id.* at ¶ 48. According to Plaintiff, this was because some CVS executives were more concerned with CVS preserving its relationship with Staples, the company which supplied coolers for the EPS Styrofoam packing system, than with implementing the

contract with Coldkeepers. *Id.* at ¶¶ 49-50. Plaintiff further alleges that some CVS executives complained of the additional time and labor required to utilize the Coldkeepers packing system. *Id.* at ¶ 51.

Coldkeepers terminated its contract with CVS in May 2014 because of CVS's alleged non-compliance with its terms and CVS's continued use of alternatives to Coldkeepers' shipping products. *Id.* at ¶ 52. The Complaint states that Relator visited CVS's Monroeville, Pennsylvania facility in the summer of 2014 and witnessed that the facility had returned to using the EPS Styrofoam packing system. *Id.* at ¶ 53. Plaintiff alleges that CVS presently continues to use the EPS Styrofoam packing system and the Styrofoam coolers supplied by Staples. *Id.*

Plaintiff alleges that, throughout the time described in the Complaint, CVS submitted claims for federal, state, and municipal reimbursement of prescription drugs costs through the following programs: Medicaid, Medicare, Medicare Part D, the Railroad Retirement Medicare Program, Federal Employees Health Benefit Programs, Tri-Care, the Civilian Health and Medical Program of the Department of Veterans Affairs, State Legal Immigrant Assistance Grants, and the Indian Health Service. *Id.* at ¶¶ 88-112. According to Plaintiff, at least some of these claims were for pharmaceuticals that had been rendered ineffective by flash freezing, which the payor would have denied had they knowledge of the pharmaceuticals' ineffectiveness. *Id.* at ¶¶ 113-122. In addition to presenting false claims to the federal government, Plaintiff alleges that CVS submitted false claims to the following states and municipalities: California, Colorado, Connecticut, Delaware, the District of Columbia, Florida, Georgia, Hawaii, Illinois, Indiana, Iowa, Louisiana, Maryland, Massachusetts, Michigan, Minnesota, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York State, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas,

Vermont, Virginia, Washington, New York City, the City of Chicago, the City of Philadelphia, and Allegheny County. *Id.* at ¶¶ 128-453.

II. Standard of Review

Within the Third Circuit, motions to dismiss under Fed. R. Civ. P. 12(b)(6) are governed by the well-established standard set forth in *Fowler v. UPMC Shadyside*, 578 F.3d 203, 210 (3d Cir. 2009).

III. Discussion

A. Plaintiff only states claim against CVS Health Corporation.

As a preliminary matter, Defendants argue that although Plaintiff names eight Defendants in the Complaint, he does not differentiate between the eight Defendants and relies on allegations directed only at "CVS," which the Complaint defines as Defendant CVS Health Corporation. Compl. at 1. Defendants claim that Plaintiff has therefore failed to meet the pleading standards in Fed. Rule Civ. P. 9(b), because Plaintiff has not "inform[ed] each defendant separately of the allegations surrounding [their] alleged participation in the fraud." *United States v. United Healthcare Ins. Co.*, 848 F.3d 1161, 1184 (9th Cir. 2016).

Plaintiff responds with case law suggesting that a lack of clarity as to the division of responsibility between Defendants is permissible at the motion to dismiss stage when "the division of responsibility and corporate structure of Defendants . . . is presumably within Defendants' knowledge." *Rosenberg v. Nassau Life & Annuity Co.*, No. CV 21-2673-KSM, 2022 WL 2718607, at *15 (E.D. Pa. July 13, 2022). Plaintiff is correct that some degree of leniency is warranted at this stage, given that Plaintiff pleaded that all Defendants fall within the same corporate structure.

But even when "corporate . . . defendants are in a better position to know the extent of each defendant's participation in the complained of conduct," all defendants still must be "given

sufficient notice of their respective roles in order that they may answer the complaint." *P & P Mktg., Inc. v. Ditton*, 746 F. Supp. 1354, 1362 (N.D. Ill. 1990). In this case, Plaintiff's Complaint provides a brief description of how each Defendant falls within CVS's corporate structure. But the specific claims set forth and prayer for relief name only a single Defendant, CVS Health Corporation. Plaintiff has not "listed the Defendants individually in varying allegations," so it is not "clear from the allegations that Relator is claiming that all . . . Defendants . . . undertook the actions described." *United States ex rel. Carter v. Halliburton Co.*, No. 1:08-CV-1162, 2009 WL 2240331, at *16 (E.D. Va. July 23, 2009).[4] I will therefore dismiss all the CVS subsidiaries, albeit without prejudice.

B. Plaintiff fails to plead a viable theory of legal falsity.

To state a claim under the FCA, a relator must show that "(1) the defendant presented or caused to be presented to an agent of the United States a claim for payment; (2) the claim was false or fraudulent; and (3) the defendant knew the claim was false or fraudulent." *Hutchins v. Wilentz, Goldman & Spitzer*, 253 F.3d 176, 182 (3d Cir. 2001). "There are two categories of false claims under the FCA: a factually false claim and a legally false claim." *U.S. ex rel. Wilkins v. United Health Grp., Inc.*, 659 F.3d 295, 305 (3d Cir. 2011). Factually false claims arise when a defendant "misrepresents what goods or services that it provided to the Government." *Id.* A claim is considered legally false when a defendant "knowingly falsely certifies that it has complied with a statute or regulation the compliance with which is a condition for Government payment." *Id.* Legally false claims may proceed under an express or implied certification theory: under the first

[4] Plaintiff has not alleged that *all* the defendants engaged in the complained-of conduct, whereas the cases on which he primarily relies concern group pleading with allegations extending to every defendant named. *See id.*; *U.S. ex rel. Trombetta v. EMSCO Billing Servs., Inc.*, No. 96 C 226, 2002 WL 34543515, at *3 (N.D. Ill. Dec. 5, 2002); *Rosenberg v. Nassau Life & Annuity Co.*, No. CV 21-2673-KSM, 2022 WL 2718607, at *15 (E.D. Pa. July 13, 2022).

theory, the defendant must have expressly certified compliance with a legal requirement to the payor, whereas under the second, the certification may have been merely implied. *Id*.

Regarding implied certifications, the Supreme Court has held that

> the implied certification theory can be a basis for liability, at least where two conditions are satisfied: first, the claim does not merely request payment, but also makes specific representations about the goods or services provided; and second, the defendant's failure to disclose noncompliance with material statutory, regulatory, or contractual requirements makes those representations misleading half-truths.

Universal Health Servs., Inc. v. United States, 579 U.S. 176, 190 (2016). Plaintiff's Complaint does not point to any specific representation about the goods or services provided that would have been rendered false by the alleged failure to comply with specific legal requirements. That in itself forecloses an implied certification theory of falsity, because the Complaint does not highlight any representations that could be misleading half-truths. *See United States ex rel. Schimelpfenig v. Dr. Reddy's Lab'ys Ltd.*, No. CV 11-4607, 2017 WL 1133956, at *5 (E.D. Pa. Mar. 27, 2017) (Jones, J.).

Likewise, as the name would suggest, an express certification theory of falsity requires that the defendant had "falsely certif[ied] that it [was] in compliance with regulations which [were] prerequisites to Government payment in connection with the claim for payment of federal funds." *Wilkins*, 659 F.3d at 305. Nowhere does Plaintiff allege that CVS made such an express certification.

In any event, it is not clear that any statutory, regulatory, or contractual requirements were violated. Plaintiff cites to various statutes and regulations in the Complaint and briefing, but Defendants are correct that many simply do not apply. Plaintiff cites to 21 U.S.C. § 351(a)(2)(b), which states that a drug:

> shall be deemed to be adulterated . . . if the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that such drug meets the requirements of this chapter as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess.

This section incorporates the current good manufacturing practice ("cGMP") regulations set forth in 21 C.F.R. Part 211. Plaintiff focuses on 21 C.F.R. § 211.142, but that section deals with warehousing and storage, rather than distribution, so it does not regulate the actions at issue here. The neighboring provision, 21 C.F.R. § 211.150, which focuses on distribution, does not mandate that pharmaceuticals stay within a certain temperature range or avoid flash freezing. Plaintiff attributes temperature-related language to § 211.150, but the language that he quotes is actually found in 21 C.F.R. § 205.50(c). And Defendants correctly note that § 205.50(c) does not apply for several independent reasons. First, that regulation is not housed within 21 C.F.R. Part 211, which includes all cGMP regulations. Additionally, that regulation establishes requirements for state licensing, applies only to wholesale distributors, and governs storage rather than transportation. *See id.* Finally, Plaintiff quotes language from 21 C.F.R. § 203.32 and § 203.36, but those are likewise not cGMP regulations, and they apply only to drug samples not intended for sale.

Plaintiff's stronger argument is based on 21 U.S.C. § 351(b), which deems a drug adulterated "[i]f it purports to be or is represented as a drug the name of which is recognized in an official compendium, and its strength differs from, or its quality or purity falls below the standard set forth in such compendium." The parties both focus on the U.S. Pharmacopeia's ("USP") section on "Good Storage and Distribution Practices for Drug Products" in their briefing.[5] U.S.P.

[5] While the USP is not attached to the Complaint or described in it, I will consider it to the extent that it is integral to Plaintiff's FCA claims. *See In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1426 (3d Cir. 1997).

36, Nat'l Formulary 31 § 1079 (2013), ECF 36-2. That section provides that "[t]he packaging . . . for the distribution of the drug product should be selected and tested to ensure that product quality is maintained and to protect the contents from the rigors of distribution including environmental or physical damage." *Id.* at 697. It further explains that "drug products in the distribution supply chain may be held at temperatures outside their labeled storage requirements as determined by an appropriate stability study." *Id.* at 699. I note that it is unclear whether the USP requirement for packaging qualifies as a standard for strength, quality, or purity, as described in 21 U.S.C. § 351(b). But it is not necessary to decide that issue now, because Plaintiff has failed to allege that Defendants made any relevant express or implied certification pertaining to this requirement. Plaintiff's legal falsity claim is therefore dismissed, with leave to amend, if Plaintiff can plausibly aver that Defendants expressly or impliedly certified compliance with an applicable statutory, regulatory, or contractual requirement.

C. Plaintiff states a claim under a "worthless services" theory of factual falsity.

In addition to providing recourse for claims that are "legally false," the FCA also recognizes "factually false" claims. "A claim is factually false when the claimant misrepresents what goods or services . . . it provided to the Government." *Foglia v. Renal Ventures Mgmt., LLC*, 754 F.3d 153, 157 (3d Cir. 2014) (quoting *U.S. ex rel. Wilkins*, 659 F.3d at 305). Typically, factual falsity FCA actions require the relator to point to specific "facts contained within the claim [that] are untrue." *United States v. Care Alts.*, 952 F.3d 89, 96 (3d Cir. 2020). And Defendants correctly note that Plaintiff has not alleged in his Complaint that CVS made specific factual misrepresentations when submitting claims for payment.

But relators can also plead factual falsity when they assert that a defendant has submitted claims for worthless goods or services. Although the Third Circuit has not addressed the

"worthless services" theory of liability under the statute, several circuits recognize it as a viable concept. *See e.g., U.S. ex rel. Absher v. Momence Meadows Nursing Ctr., Inc.*, 764 F.3d 699, 709-10 (7th Cir. 2014); *Mikes v. Straus*, 274 F.3d 687, 702 (2d Cir. 2001), *abrogated on other grounds*, *Universal Health Servs.*, 579 U.S. at 186; *U.S. ex rel. Lee v. SmithKline Beecham, Inc.*, 245 F.3d 1048, 1053 (9th Cir. 2001); *Chesbrough v. VPA, P.C.*, 655 F.3d 461, 468-69 (6th Cir. 2011); *U.S. ex rel. Roop v. Hypoguard USA, Inc.*, 559 F.3d 818, 824 (8th Cir. 2009). Where it is recognized, "the performance of the service [must be] so deficient that for all practical purposes it is the equivalent of no performance at all." *Mikes*, 274 F.3d at 703. It "is not enough to offer evidence that the defendant provided services that are worth some amount less than the services paid for. That is, a 'diminished value' of services theory does not satisfy this standard. Services that are 'worth less' are not 'worthless.'" *Absher*, 764 F.3d at 710.[6]

After careful review of Plaintiff's Complaint, I conclude that he has successfully pled a "worthless services" theory of falsity, even if one accepts CVS's position that such a claim may be difficult to prove going forward. The Complaint states that "the flash freezing of many of the temperature sensitive pharmaceuticals shipped by Defendant CVS renders these pharmaceuticals defective and unusable according to the manufacturers' 'Medication Guide' for those particular pharmaceuticals." Compl. at ¶ 82. Furthermore, according to Plaintiff, Humira's Medication Guide states: "**Do not** freeze HUMIRA. **Do not** use HUMIRA if frozen, even if it has been thawed." *Id.* at ¶ 83 (emphasis in Medication Guide). Enbrel's Medication Guide states: "**Do not freeze**." *Id.* at ¶ 85 (emphasis in Medication Guide). And Copaxone's Medication Guide states: "Never freeze your COPAXONE Pre-filled syringes. If they do accidentally freeze, do not use,

[6] This line of cases led a panel of the Third Circuit, in a non-precedential decision, to observe that "[c]ase law in the area of 'worthless services' under the FCA addresses instances in which either services literally are not provided, or the service is so substandard as to be tantamount to no service at all." *In re Genesis Health Ventures, Inc.*, 112 F. App'x. 140, 143 (3d Cir. 2004).

and discard in a proper container." *Id.* at ¶ 86. What's more, the Complaint states that "CVS's customer service representatives were trained to advise patients to discard any medications that had appeared to be frozen and obtain a replacement for the medications." *Id.* at ¶ 33.

CVS argues that the Complaint is internally inconsistent when it alleges that the freezing process "reduc[ed] [the] efficacy" of medications, and that shipment in the EPS Styrofoam packing system could "reduce the shelf life of the medication, diminish the physical integrity of the medication and cause the partial or total loss of the effectiveness of the medication," *id.* at ¶¶ 34-35, because such a medication is not "worthless." But this overlooks the nature of the products that are the subject of this case. The claim here is not that the service life of a piece of equipment is less than advertised. The focus is on products that are important for human health. Medications are scientifically designed to deliver a particular therapeutic dose. Medically, it would be unsound to administer anything less than that dose. That is undoubtedly why recipients of frozen medication were advised, through customer service representatives and medication guides, to dispose of frozen medications and obtain replacements. By definition, discarded medication does nothing for a patient regardless of whether the medication had only partially or completely lost its potency. Construing the Complaint in the light most favorable to the plaintiff, *Fowler*, 578 F.3d at 210, I conclude that some of the pharmaceuticals for which Defendants submitted claims were, in fact, medically worthless. I therefore conclude that Plaintiff's FCA claims may proceed under a "worthless services" theory of falsity.

D. Plaintiff has pled "materiality."

For a claim to be actionable under the FCA, "a misrepresentation about compliance with a statutory, regulatory, or contractual requirement must be material to the Government's payment

decision."[7] *Universal Health Servs.*, 579 U.S. at 192. The FCA defines "material" as "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." 31 U.S.C. § 3729(b)(4). The Supreme Court has explained that,

> when evaluating materiality under the False Claims Act, the Government's decision to expressly identify a provision as a condition of payment is relevant, but not automatically dispositive. Likewise, proof of materiality can include, but is not necessarily limited to, evidence that the defendant knows that the Government consistently refuses to pay claims in the mine run of cases based on noncompliance with the particular statutory, regulatory, or contractual requirement. Conversely, if the Government pays a particular claim in full despite its actual knowledge that certain requirements were violated, that is very strong evidence that those requirements are not material. Or, if the Government regularly pays a particular type of claim in full despite actual knowledge that certain requirements were violated, and has signaled no change in position, that is strong evidence that the requirements are not material.

Universal Health Servs., 579 U.S. at 194-95. Courts evaluate several relevant factors when determining materiality:

> (1) whether the government expressly designates compliance with a particular statutory, regulatory, or contractual requirement as a condition of payment; (2) the government's response to noncompliance with the relevant contractual, statutory, or regulatory provision; and (3) whether the defendants' alleged noncompliance was 'minor or insubstantial.'

United States ex rel. Foreman v. AECOM, 19 F.4th 85, 110 (2d Cir. 2021) (quoting *Universal Health Servs.*, 579 U.S. at 194-95).

Plaintiff has not pled any facts that are relevant to the first two factors, and Defendants argue that Plaintiff has not "identified any relevant legal obligation or factual statement to suggest

[7] I note that the materiality requirement must be applied somewhat differently under a "worthless services" theory of falsity, because "a worthless services claim does not require an affirmative misrepresentation; rather, a worthless services claim is premised on the deficiency of the services provided to the government." *U.S. ex rel. Davis v. Prince*, 753 F. Supp. 2d 569, 592 (E.D. Va. 2011).

that temperature excursions during shipment have anything to do with 'the bargain' between CVS and the federal government, much less that they go to its 'essence.'" Reply at 12, ECF 46.

In many cases, this would be fatal to a relator's claim. But a "worthless services" theory of liability does not require relators to identify specific legal obligations or factual statements, because, as discussed above, such a theory rests on the presumption that the government would not willingly pay claims for good and services when they are so substandard as to be tantamount to no service at all. Where a medication has been frozen, and its supplier expressly warns against using medication that has been frozen, it would seem self-evident that the government would properly decline to pay for such shipments. As a result, I conclude that the alleged noncompliance in the form of providing worthless services is substantial enough to establish materiality.

E. Plaintiff has pled "knowledge."

Defendants can only be held liable under the FCA if they acted "knowingly." 31 U.S.C. § 3729(a)(1); *see Hutchins*, 253 F.3d at 182. The FCA defines "'knowing' and 'knowingly' to mean that a person has 'actual knowledge of the information,' 'acts in deliberate ignorance of the truth or falsity of the information,' or 'acts in reckless disregard of the truth or falsity of the information.'" *Universal Health Servs.*, 579 U.S. at 182 (quoting 31 U.S.C. § 3729(b)(1)(A)). To be held liable, "the defendant [must have] knowingly violated a requirement that the defendant knows is material to the government's payment decision." *Id.* at 181.

According to Plaintiff, CVS conducted testing on Humira, Enbrel, and Copaxone, which revealed that CVS's EPS Styrofoam packing system resulted in those medicines flash freezing. Compl. at ¶¶ 36-42. This information made its way to several CVS executives. *Id.* at ¶ 44. CVS then "contemplated doing further chromatography testing to see if medications that had flash frozen had lost potency or efficacy but they declined to do so in part because of the costs of the

testing which could be several thousand dollars per test." *Id.* at ¶ 43. Furthermore, as mentioned above, the Medication Guide for each of these three pharmaceuticals specifically warned that they should not be frozen, and CVS trained its customer service representatives to advise patients to discard any medications that had appeared to be frozen and obtain replacements.

These allegations support the notion that CVS knew of a flash freezing problem with its method of shipping these three pharmaceuticals, and either knew or acted in deliberate ignorance of the fact that such freezing made the medications worthless. Because CVS knew that the freezing issue warranted disposing of the medication, I further conclude that it Plaintiff has pleaded its knowledge of the materiality of the issue. *Cf. Universal Health Servs.*, 579 U.S. at 191 (discussing a hypothetical claim for reimbursement related to guns, and emphasizing that "because a reasonable person would realize the imperative of a functioning firearm, a defendant's failure to appreciate the materiality of that condition would amount to 'deliberate ignorance' or 'reckless disregard' of the 'truth or falsity of the information'" even if the Government did not specify that the guns must be able to shoot).

F. Plaintiff has pled claims regarding Humira, Enbrel, and Copaxone with particularity.

In addition to challenging whether Plaintiff has pled the elements of an FCA claim, Defendants make several arguments to the effect that Plaintiff has not pled his FCA claims with particularity.

First, Defendants argue that Plaintiff has failed to state with particularity the circumstances constituting fraud because he has not "identif[ied] any shipment by CVS that actually experienced a temperature excursion, any patient who received such a shipment, any instance in which such a patient's medication was affected by the supposed temperature excursion, or any request that CVS

made for government payment for such a medication." Memo. in Supp. of Mot. at 20-21, ECF 36-1. But neither the FCA nor Fed. R. Civ. P. 9(b) require as much at the pleading stage.

The Third Circuit has held that "it is sufficient for a plaintiff to allege 'particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted.'"[8] *Foglia*, 754 F.3d at 156 (quoting *United States ex rel. Grubbs v. Kanneganti*, 565 F.3d 180, 190 (5th Cir. 2009)). Plaintiff has done so. As detailed above, Plaintiff has alleged facts that, if true, lead to the strong inference that Defendants submitted claims to Medicare and other government payors for medication that had been flash frozen and was therefore worthless. No more is required at this stage in litigation.

But Defendants are correct that Plaintiff's claims must be limited in one respect. While Plaintiff seemingly intends to state a claim for all pharmaceuticals that CVS shipped during the relevant time period, he has only pled specific facts for three: Humira, Enbrel, and Copaxone. Plaintiff cannot proceed with FCA claims related to any medications that he has not provided specific factual allegations for. *See In re Rockefeller Ctr. Properties, Inc. Sec. Litig.*, 311 F.3d 198, 217 (3d Cir. 2002) ("Rule 9(b) requires, at a minimum, that plaintiffs support their allegations of . . . fraud with all of the essential factual background that would accompany 'the first paragraph of any newspaper story'—that is, the 'who, what, when, where and how' of the events at issue.") (quoting *In re Burlington Coat Factory*, 114 F.3d at 1422). As a result, to the extent that Plaintiff seeks to claim violations of the FCA for medications other than Humira, Enbrel, and Copaxone, such claims are dismissed without prejudice.

[8] Courts within this Circuit have further explained that "[a]n FCA claimant is not required to show 'the exact content of the false claims in question' to survive a motion to dismiss, as 'requiring this sort of detail at the pleading stage would be "one small step shy of requiring production of actual documentation with the complaint, a level of proof not demanded to win at trial and significantly more than any federal pleading rule contemplates."'" *United States ex rel. Behnke v. CVS Caremark Corp.*, No. CV 14-824, 2020 WL 1953626, at *5 (E.D. Pa. Apr. 23, 2020) (Goldberg, J.) (quoting *Foglia*, 754 F.3d at 156).

I reject Defendants' other arguments seeking to limit Plaintiff's claims. First, Defendants argue that no kind of shipment or shipping method is at issue other than shipments by a mail-order pharmacy to a patient directly. Memo. in Supp. of Mot. at 22. But this ignores allegations that Defendant CVS has used the same allegedly ineffective packing system for shipments to "doctors, patients, and clinics," not just mail-order shipments to patients. Compl. at ¶¶ 28, 31.

Likewise, Defendants argue that Plaintiff's claims should be limited to the time period of March 2012 to March 2013, the time between CVS allegedly learning of the flash freezing problem and its awarding Coldkeepers the contract to use its replacement system. But Plaintiff has alleged that CVS continued to use the ineffective packing system after contracting with Coldkeepers and that it continues to use such a substandard system to this day. Plaintiff has further alleged reasons why CVS did not comply with its Coldkeepers contract. I am therefore not convinced that discovery should be limited to the time period of March 2012 to March 2013.

G. Plaintiff fails to state a claim under Maryland, Michigan, New Hampshire, New York City, and Philadelphia law.

Defendants raise several arguments challenging Plaintiff's state and municipal claims. To begin, both sides agree that Plaintiff's claim under the Maryland False Health Claims Act of 2010 (Count Sixteen) should be dismissed, as should one of Plaintiff's duplicative claims under Michigan law (Count Nineteen). Count Sixteen and Nineteen are accordingly dismissed with prejudice.

Defendants further argue that Plaintiff has failed to plead any of his state or municipal claims with particularity and has relied on conclusory statements throughout, warranting their dismissal. This broad-brush argument misses the mark. For each state and municipal claim, Plaintiff has stated the "who, what, when, where and how" of the events at issue—as required to plead fraud under Fed. R. Civ. P. 9(b)—and has specifically alleged that Defendants submitted

false claims to state payors. *In re Rockefeller Ctr. Props., Inc. Sec. Litig.*, 311 F.3d at 217; *see United States ex rel. Bates v. Dentsply Int'l, Inc.*, No. 12-7199, 2014 WL 4384503, at *10 (E.D. Pa. Sept. 4, 2014) (Bartle, J.) (dismissing state law claims where relators "failed to allege location-specific facts"); *United States ex rel. Forney v. Medtronic, Inc.*, No. 15-6264, 2017 WL 2653568, at *5 (E.D. Pa. June 19, 2017) (Smith, J.) (dismissing state law claims where the relator "only mentions other states [when referring to the] causes of action under the laws of those states"); *Foglia v. Renal Ventures Mgmt.*, LLC, 830 F. Supp. 2d 8, 23 (D.N.J. 2011) (dismissing state law claims where "Relator . . . does not clearly allege that false or fraudulent claims were submitted to . . . state payors."). Dismissal of all state and municipal claims for failure to plead with particularity is not justified, though I will subject Plaintiff's state and municipal claims to the same limitations as his federal FCA claims.

Moving to Defendants' specific arguments, they are correct that Plaintiff fails to state a claim under the New Hampshire False Claims Act (Count Twenty-Three). The New Hampshire law allows individuals to bring suit

> in the name of the state against a defendant that (1) has its principal place of business within the state or (2) during the during the 12-month period immediately preceding the date the action is filed, received reimbursement from the Medicaid program of this state, as defined under RSA 167:63, V, equal to 10 percent or more of the defendant's aggregate reimbursement from all state medical assistance programs governed by Title XIX of the Social Security Act.

N.H. Rev. Stat. § 167.61-c(II)(a). Plaintiff does not plead facts to satisfy either condition for suit, nor does Plaintiff respond to Defendants' argument that suit under the New Hampshire False Claims Act is improper. Count Twenty-Three is therefore dismissed with prejudice.

Plaintiff likewise fails to state a claim under both the New York City False Claims Act (Count Thirty-Seven) and City of Philadelphia False Claims Act (Count Thirty-Nine). The New York City Act requires relators to receive authorization to proceed from the NYC Corporation

Counsel by first submitting a proposed civil complaint to the Corporation Counsel. N.Y. Admin. Code § 7-804(b)-(e). The Philadelphia Act in turn requires relators to receive authorization to proceed from the City Solicitor by first submitting a proposed civil complaint to the Solicitor. Phila. Code § 19-3603. Plaintiff does not allege to have done either, and these claims therefore lack validity under the respective acts.

On the other hand, I conclude that Plaintiff does state a claim under the New Mexico Medicaid False Claims Act (Count Twenty-Five), despite Defendants' arguments to the contrary. The New Mexico law only allows claims by relators that are "affected person[s]," which the Defendants argue Ellis is not. N.M. Stat. § 27-14-7(B). While the statute does not define "affected person[s]," courts in the Third Circuit have stated that the term should not be interpreted "in the narrowest sense as only referring to New Mexico citizens," further holding that the term encompasses employees and former employees of a defendant. *U.S. ex rel. Cestra v. Cephalon, Inc.*, No. CIV.A. 14-1842, 2015 WL 3498761, at *15 (E.D. Pa. June 3, 2015) (O'Neill, J.). Because Plaintiff's company Coldkeepers allegedly contracted with CVS to provide effective packaging material that CVS did not use during the relevant time period, I conclude that Plaintiff is an "affected person" within the broad terms of the New Mexico statute.

Defendants further argue that the New Mexico law bars claims where New Mexico has not found, in writing, substantial evidence of a violation. N.M. Stat. § 27-14-7(E)(2). But a motion to dismiss an original complaint is not the appropriate time to resolve this issue under New Mexico law, because New Mexico makes its substantial evidence determination *after* the filing of a complaint. *See United States ex rel. Wood v. Allergan, Inc.*, 246 F. Supp. 3d 772, 832 (S.D.N.Y. 2017), *rev'd and remanded on other grounds*, 899 F.3d 163 (2d Cir. 2018) ("But while those provisions may well doom Wood's New Mexico and Delaware claims in the long run, they are not

a valid basis for dismissal under Rule 12(b)(6), as they require consideration of matters outside of the record."); *U.S. ex rel. King v. Solvay S.A.*, 823 F. Supp. 2d 472, 520 (S.D. Tex. 2011), *order vacated in part on reconsideration on other grounds*, No. CIV.A. H-06-2662, 2012 WL 1067228 (S.D. Tex. Mar. 28, 2012). The analysis is different when relators have filed amended complaints after the state has had opportunity to make its substantial evidence determination, but that is not the case here. *See U.S. ex rel. Cestra v. Cephalon, Inc.*, No. CIV.A. 14-1842, 2015 WL 3498761, at *14 (E.D. Pa. June 3, 2015) (deciding this issue on a motion to dismiss only because relator had filed a second amended complaint and thus "had the opportunity to determine and allege in the second amended complaint whether New Mexico issued him a determination of substantial evidence that its FCA statute was violated."); *U.S. ex rel. Streck v. Allergan, Inc.*, 894 F. Supp. 2d 584, 603 (E.D. Pa. 2012), *aff'd sub nom. United States v. Allergan, Inc.*, 746 F. App'x 101 (3d Cir. 2018) (deciding the issue on a motion to dismiss a fourth amended complaint). Because Plaintiff has not had the opportunity to allege whether New Mexico made a substantial evidence determination after the filing of the Complaint, dismissal of the New Mexico claim on those grounds is not warranted.

IV. Conclusion

For the reasons set forth above, Defendants' Motion to Dismiss is granted in part and denied in part. All Defendants except for CVS Health Corporation will be dismissed without prejudice. Plaintiff's "legal falsity" claims will be dismissed without prejudice, and its "factual falsity" claims are limited to a "worthless services" theory of falsity pertaining to the drugs Humira, Enbrel, and Copaxone. Plaintiff's claims under the New Hampshire False Claims Act, the New York City False Claims Act, and the City of Philadelphia False Claims Act will be

dismissed with prejudice, and his claims under Maryland and Michigan law set forth in Counts Sixteen and Nineteen will be dismissed with prejudice also. An appropriate Order follows.

/s/ Gerald Austin McHugh
United States District Judge